REPORT TITLE

The 30-Day Response by the Endosulfan Task Force to the Health Effects Division Risk Assessment for the Endosulfan Reregistration Eligibility Decision Document Dated February 2, 2000

DATA REQUIREMENT

Not Applicable

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STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS

No claim of confidentiality is made for any information contained in this study on the basis of its falling within the scope of FIFRA §10(d)(1)(A), (B), or (C).

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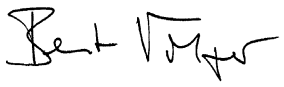
STATEMENT OF GOOD LABORATORY PRACTICE

No Good Laboratory Practice Statement is required for the information presented in this volume according to 40CFR Part 160.



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I. INTRODUCTION

Aventis CropScience has prepared this 30-day response to the Health Effects Division (HED) risk assessment for the endosulfan reregistration eligibility decision document (HED memo by Stephen C. DeVito, dated February 17, 2000; Barcode D250471). The response is prepared for, and submitted by, the Endosulfan Task Force companies consisting of Aventis CropScience USA LP, FMC Corporation and Makhteshim-Agan of North America. The Task Force is addressing only those issues related to the products, application methods, use sites and used rates that are supported by the Task Force companies. The use sites supported by the Task Force include agricultural crops, outdoor commercial tree and ornamental crops, and greenhouse tomatoes. The agricultural crops will only include those crops not covered by the use-deletion requests published or submitted by the Task Force companies since the Data Call In issue by EPA in May, 1994 (62FR p.5398-5399, February 5, 1997 and use-deletion requests by Task Force members in July to November, 1999). The methods of application supported by the Task Force are groundboom application, aerial application, chemigation, and airblast application. The formulations supported by the Task Force are the emulsifiable concentrate liquid formulation and the wettable powder formulation packaged with and without water-soluble packaging. It should be noted that the response by the Task Force does not address the exposure issues identified by the HED risk assessment resulting from use scenarios not supported by the Task Force. These include the residential or other structural uses of endosulfan, hand applications, and dust formulations or the smoke canister formulation which are not supported by the Endosulfan Task Force and the therefore beyond the scope of the Task Force response.

We have noted that the current HED Chapters for endosulfan have not included the contents or Agency reviews for several key human exposure-related reports submitted by the Task Force during the period of October-November, 1999. As noted in the Task Force Response (see Section VII), the submitted studies include the reports titled as: 'Evaluation of Possible Endocrine Effects of Endosulfan in Mammalian Species' (MRID No. 44939102); 'Assessment of Human Exposure from the Application of Endosulfan' (MRID No. 44939101); 'Calculation of Dietary Exposure via Drinking Water and Comparison to the Drinking Water Level of Concern' (MRID No. 44953105); the "Magnitude of Endosulfan Residue in or on Rotational Crops Resulting from Two Applications of Phaser Insecticide, USA, 1998 (MRID No.: 44972301); and "Magnitude of Endosulfan Residues in or on Wheat Grain and Processed Commodities Resulting from Two applications of Phaser® Insecticide in an Exaggerated Rate, USA, 1998" (MRID No.: 44762901). The Task Force response has made references to these recently submitted studies and request that Agency will review and include these additional information in the next revised HED Chapters for the endosulfan RED.

II. TASK FORCE RESPONSE TO THE HED SECTION FOR THE PHYSICOCHEMICAL PROPERTIES CHARACTERIZATION OF ENDOSULFAN

TASK FORCE RESPONSE TO THE HED SECTION FOR THE PHYSICO-CHEMICALPROPERTIES CHARACTERIZATION OF ENDOSULFAN PHYSICOCHEMICAL PROPERTIES CHARACTERIZATION

RE: Endosulfan: HED Risk Assessment for the Endosulfan RED Document (DP Barcode: D250471; Memo by Stephen C. DeVito, Ph.D., dated February 17, 2000). Section 2.0 Physicochemical Properties Characterization (pages 10-14)

The Endosulfan Task Force (ETF) noted that some Agency statements within the HED Section (2.0) that are not consistent with the available data for the physicoehemical and environmental fate properties of endosulfan. Therefore, the ETF is providing the following comments and requests that the Agency will review the contents, and revise this section where appropriate before releasing the HED documents in the Public Docket.

Page 11, 1st paragraph.

EPA indicates that endosulfan has very low water solubility (about 0.1 mg/L at 25°C) but appreciable lipophilicity.

ETF comments: The ETF notes that according to data provided in our submissions, the water solubility is 0.33 mg/L and the octanol water partition coefficient (log P) = 4.77 (Study Record No.: A36576)

Page 13, 1st paragraph

ETF comments: We note that the summary of the environmental fate of endosulfan, currently based upon the Hazardous Substances database will be modified once EFED's review of endosulfan become available. For example we note that the statement concerning the half-lives of α and β endosulfan in soil (given as "approximately 57 days and 208 days" respectively) are in fact the **upper 90 percentile values** based on the complete registration database.

Page 13, 3rd Paragraph

EPA states that endosulfan is a chlorinated hydrocarbon.

ETF comments: While the general chemical structure of endosulfan suggests that this compound might be just another organo-chlorine, in both chemical and biological criteria, the behavior of endosulfan is distinctly different from that of the "typical" organo-chlorines". Because of its chemical/biological characteristics, endosulfan has been classified as a "*sulphite*" or as "*dioxathiepin*" by IUPAC and in the Chemical Abstracts. Further, the World Health Organization (WHO) has confirmed this by classifying endosulfan as the "*sulfurous acid ester of a chlorinated cyclic diol*".

Page 13, 4th Paragraph

EPA notes that endosulfan is a polychlorinated "cyclodiene-type" pesticide structurally related to chlordane, heptachlor, aldrin, endrin and dieldrin, and that these compounds are no longer registered for use as pesticides in the United States.

ETF comments: We do not see the relevance of this paragraph in a section devoted to characterizing the physicochemical characteristics of endosulfan. In fact a comparison of the basic environmental fate properties of these compounds clearly identifies endosulfan as less persistent than the other " cyclodiene-type" insecticides which is a key factor in the continued registration of endosulfan and the cancellation of the registration of the other compounds. The previous paragraph on page 13 actually states that "EPA and other government institutions have not characterized endosulfan as a persistent bioaccumulating toxic substance. The following table based on values in the USDA-ARS database highlights the differences between endosulfan and the other insecticides. Endosulfan is of higher water solubility and is significantly less persistent than each of other polychlorinated cyclodiene insecticides.

Compound	Solubility (ppm)	Log Kow	K_{OC}	Field dissipation Half-Life (Range) (days)
Endosulfan	0.33	4.77	11,000	60 (12 – 176)
Chlordane	0.056	6.0	60,000	365 (283 – 3500
Dieldrin	0.14	4.55	12,000	1000 (225 – 1260)
Aldrin	0.027	5.52	17,500	365 (10 – 1237)
Heptachlor	0.056	4.4-5.5	24,500	250 (40 – 1277)

While the partition coefficient (log K_{OW}) may suggest similar bioaccumulation potential, Endosulfan differs in its bioaccumulation behavior in that it is rapidly depurated after uptake with most of the orally dosed endosulfan excreted within two days. This behavior was observed in a number of studies with a range of different organisms including fish, mollusks, chicken, rats, goats, and cows. It was especially this depuration behavior which caused other authorities to NOT classify endosulfan as a bioaccumulating substances, as was correctly stated by EPA in the third paragraph on page 13.

The ETF therefore suggests that this last paragraph of page 13 should be deleted as it is not relevant to the discussion of endosulfan or else a full comparison with the environmental fate properties of the other listed compounds is made.

III. ENDOSULFAN TASK FORCE RESPONSE TO THE HED TOXICOLOGY CHAPTER

ERRORS IN HEALTH EFFECTS DIVISION (HED) RISK ASSESSMENT FOR THE ENDOSULFAN REREGISTRATION ELIGIBILITY DECISION DOCUMENT, DATED FEBRUARY 2, 2000

TOXICOLOGY CHAPTER

RE: Endosulfan: HED Risk Assessment for the Endosulfan RED Document (DP Barcode: D250471; Memo by Stephen C. DeVito, Ph.D., dated February 17, 2000) - Exposure Assessment,Section 3.0 "Hazard Characterization" and Related Documents;

Endosulfan079401: Toxicology Chapter for the Reregistration Eligibility Document (HED memo by Nicole C. Paquette, Ph.D. dated November 22, 1999.

The Endosulfan Task Force (ETF), comprised of Aventis CropScience, FMC, and Makhteshim-Agan North America, respectfully submit the following comments in response to the above referenced draft chapter. While these comments do not respond strictly to errors, they do provide the agency with a brief summary of the key areas of concern with regard to toxicity endpoints for endosulfan.

There are three key areas of concern regarding the EPA's review of the endosulfan toxicity data that the ETF will address. These areas are:

- The NOEL selection for the 21-day dermal study in rats,
- requirement of a developmental neurotoxicity study and retention of a FQPA safety factor of 3x due to uncertainty associated with this data gap, and
- EPA's suggestion that endosulfan may be an endocrine disruptor.

The following is a brief summary of the significant points regarding the above mentioned areas of concern. A more complete response will be provided in the 60-day response period for the final draft of the HED chapter.

1. NOEL selection for the 21-day dermal study in rat

EPA Conclusion

"*The endpoint for the short-term, intermediate- and long-term dermal exposure assessment was based on hepatotoxicity seen in a 21-day study in which endosulfan was applied dermally to rats (NOAEL = 3.0 mg/kg/day).*" (HED chapter, p. 4)

The HED selection was based on the HIARC report (ENDOSULFAN 079401: Toxicology Chapter for the Reregistration Eligibility Document. Nicole Paquette memo dated 2/9/00).

The HIARC report concluded that *"for systemic toxicity, the NOAEL was 3 mg/kg/day and the LOAEL was 9 mg/kg/day based on increased mortality in males, and increased liver abnormalities (enlargement of parenchymal cells, loss of cytoplasmic basophilia and isolated cell necrosis and frequent mitosis) in both sexes."*

ETF Response

There are four 21-dermal studies in rats that support a NOEL of 9 mg/kg/day for endosulfan. The Agency reviewed three of these studies, two using technical material (ACC# 257682, 257683; MRID# 00147744) and a third using formulated endosulfan at 49.5% purity (MRID# 41048506). In addition, there is a fourth study using an emulsifiable concentrate formulation (MRID# 41048505), which is the preferred commercial product for endosulfan.

In the study selected by EPA to establish the dermal NOEL, the Agency cited two effects at 9 mg/kg/day: increased mortality in males and liver abnormalities in both sexes. The increased mortality consisted of two of six males at the 9 mg/kg/day dose level that died on days 5 and 8. Necropsy revealed that the first male's testes, spleen and thymus were significantly reduced in size (immature) with no evidence of inflammation and/or atrophy. The second male also showed marked reduction in size of the testes, seminal vesicles and liver, without signs of inflammation or atrophy. These effects were considered evidence of a pre-existing, non-treatment-related developmental disturbance, and the deaths should not be considered in the overall toxicological evaluation for endosulfan. No mortalities were seen in male rats at the next highest dose of 27 mg/kg/day, and in the other three dermal studies the lowest dose that produced mortality in male rats was 81 mg/kg/day.

The liver abnormalities cited at 9 mg/kg/day consisted of enlargement of parenchymal cells in peripheral sections, together with loss of cytoplasmic basophilia, isolated cell necroses, and frequent mitosis. However, a thorough review of this study shows that these effects were considered "very slight" by the pathologist, were only seen in a few animals, and were neither sex- nor dose-related.

Based on this information, the ETF believes that the appropriate NOAEL for this study is 9 mg/kg/day, as was concluded in the original study report.

In addition, if all four available subchronic dermal studies for endosulfan are evaluated together, the weight-of-evidence clearly supports a NOAEL of 9 mg/kg/day. A review of the studies will reveal that they were all:

- Conducted using the same strain of rat, and dosing period (21 days)
- Reviewed and accepted as guideline studies by EPA
- Consistently support a NOEL of 9 mg/kg/day, based on clinical signs of toxicity and increased mortality in females at doses of 12 mg/kg/day and higher.

The ETF, therefore, concludes that the appropriate NOAEL for the evaluation of short-term, intermediate- and long-term dermal exposures to endosulfan is 9 mg/kg/day.

2. Requirement of a Developmental Neurotoxicity Study and Retention of a 3x FQPA Safety Factor.

EPA Conclusion

"*The toxicology data gaps for endosulfan technical are a subchronic neurotoxicity assay and a developmental neurotoxicity assay."* (HED chapter, p.3)

"*Results from developmental and reproductive toxicity studies conducted under OPPTS guidelines do not show increased or special sensitivity of the fetus or offspring to the toxicity of endosulfan. Results from the reproductive study raise a possible qualitative concern, however, regarding special sensitivity. …In addition, results from an open literature study suggest special sensitivity. The default statutory tenfold (10x) FQPA safety factor was retained at threefold (3x) for those subpopulations comprised of infants, children, and females of child-bearing age."* (HED chapter, p. 3)

HED and the FQPA Safety Factors Committee (B. Tarplee memo dated 11/20/98) based their recommendations on the following:

1) fetal effects reported in the open literature abstract (Lakshmana, M.K. and Raju, T.R., 1994);
2) the severity of effects seen in the female offspring of the F_0 generation (increased pituitary) and the F_1b generation (increased uterine weights) at the high-dose when compared to the toxicity observed in parental animals (decreased body weight) at this dose in the two generation reproduction study in rats; and
3) The subchronic neurotoxicity study (requested by the HIARC) will only address the neuropathological concerns resulting from exposure to endosulfan – a developmental neurotoxicity study will provide the critical data demonstrating the toxic effects of endosulfan on the developing fetal nervous system.

ETF Response

The ETF does not concur with HED's conclusion that a developmental neurotoxicity study is required for endosulfan or that a FQPA safety factor of 3x should be retained due to uncertainty associated with this data gap. A developmental neurotoxicity study should not be required for endosulfan based on the weight-of-evidence that has been presented in the HIARC report:

- Both the FQPA Safety Committee and HIARC concluded that *"based on the results of animal studies conducted under OPPTS guidelines there is no evidence of increased sensitivity or susceptibility of the fetus, infants or children to the toxicity of endosulfan."* (HED chapter, p.3)

- HED's Safety Factor Committee also concluded earlier that *"1) there is no evidence of increased susceptibility in any study; 2) the severity of the fetal effects in the reproduction study were not consistent between generations and the target organ toxicity seen in this study was not seen in any other study; and 3) reliable data and conservative assumptions in screening level models were used to assess the potential dietary (food and water) and residential exposure to this chemical. Consequently the FQPA safety factor was reduced based on the uncertainty associated with the data gap for a developmental neurotoxicity study in rats."* (B. Tarplee memo, p.5)
- "*There was no evidence of abnormalities in the development of the fetal nervous system in the pre/post natal studies. Neither brain weight nor histopathology (perfused or non-perfused) of the nervous system was affected in the subchronic and chronic toxicity studies."* (HIARC report, p. 26)
- Weight effects of the pituitary gland and uterus in the F_0 and F_1b pups, respectively, could not be correlated to any resulting histopathology; were not considered severe when compared to the maternal effects by the HIARC Committee; were not consistent across generations; were not shown to be target organs of toxicity in any other subchronic or chronic study; did not affect any developmental or reproductive endpoints in either generation; and are not generally associated with neurotoxicity endpoints of concern.
- GLP studies should provide a greater weight-of-evidence in the determination of sensitivity to infants and children, than a non-GLP public literature abstract which has not undergone a thorough review by the Agency.

Therefore, the ETF believes that the available data adequately addresses the concern for sensitivity to children and infants, and neither a developmental neurotoxicity study nor a FQPA safety factor of 3x should be required for endosulfan.

3. EPA's suggestion that Endosulfan is an Endocrine Disruptor

EPA Comment

> "Results from some studies suggest that endosulfan may be an endocrine disruptor." *(HED chapter, p.3)*

"Reports in the open literature suggest that endosulfan may affect hormone metabolism and endocrine function. In studies submitted to the Agency, treatment-related effects were seen in the two-generation reproduction study in rats (MRID#00148264) characterized as increases in the pituitary glands weight and uterine weights in female offspring that may affect the neuroendocrine control. In a chronic feeding study in rats, high doses of endosulfan induced testicular atrophy with necrosis of the germinal lining of the seminiferous tubules which could result in possible spermatogenesis. In a carcinogenicity study, there was increased incidences of parathyroid hyperplasia in male rats (MRID#41099502). *"Male rats fed high doses of endosulfan for 15 to 30 days had significantly inhibited testicular androgen biosynthesis. In in-vitro bioassays, endosulfan was shown to have estrogenic properties comparable to those of DDT and chlordecone and binds to the progesterone receptor as well as estrogen receptor."* (HIARC report, p.24)

ETF Response

While the ETF will not address all of the specific points referenced in the HIARC report during this comment period, we would refer the agency to a submission by the ETF (Bremmer J.N. and Leist K.-H., dated 12/18/98; MRID 44939102, submitted on October 4, 1999) which provides a review of the current toxicity data, both public literature and regulatory guideline studies, for identification of potential endocrine effects by endosulfan. There is no indication from the available data to support the HIARC supposition that endosulfan may effect neuroendocrine control or spermatogenesis. Nor is there any indication of a negative effect on the biosynthesis of gonadal hormones.

The ETF request that EPA removes references to potential endocrine disruption from the endosulfan document until all relevant data have been reviewed and the Agency completes their development of guidance concerning the evaluation and classification of these effects.

IV. ENDOSULFAN TASK FORCE RESPONSE TO THE HED RESIDUE CHEMISTRY CHAPTER

ENDOSULFAN TASK FORCE RESPONSE TO HED's RISK ASSESSMENT FOR THE ENDOSULFAN REREGISTRATION ELIGIBILITY DECISION DOCUMENT, DATED FEBRUARY 2, 2000

RESIDUE CHEMISTRY CHAPTER

RE: Revised Residue Chemistry Chapter for The Endosulfan Reregistration Decision Document (DP Barcode: D250489; Memo by John S. Punzi, Ph.D., dated January 18, 2000) - Exposure Assessment, Section 4.3 "Risks from Dietary (Food and Drinking Water Sources) Exposure to Endosulfan",

The Endosulfan Task Force (ETF) appreciates EPA thorough review of the endosulfan data package and preparation of the RED document. Comments regarding Residue Chemistry are given below especially addressing areas where additional data have been requested.

GLN 860.1360 Multiresidue Methods

EPA Comments: Recovery data for parents and metabolites through PAM I methodologies are required.

ETF Response: **The** established PAM I methods for endosulfan were used in the submitted residue studies to analyze the endosulfan parents and the sulfate metabolite. Therefore we believe that no additional recovery data should be required.

GLN 860.1380 Storage Stability Data – Plants

EPA Comments: Additional storage stability data required for an oilseed and a non-oily grain, as well as their processed commodities.

ETF Response: We have developed the storage stability data on wheat and processed fractions and the report is near completion. The report will be submitted to the Agency in the near future. Oilseed crop storage stability data are not required since the ETF does not support the rapeseed tolerance (reference: use-deletion request submitted by Task Force member companies in July to November 1999).

GLN 860.1480 Meat, Milk, Poultry, Eggs

The ETF agrees with the Agency finding that the registration requirements for animal feeding studies are fulfilled. However, the Task Force does not agree with the calculation of the maximum dietary burden for cattle using the pineapple-processed residue as 20% to 30% of the diet. Use of this commodity in the cattle diet would be very localized since the only US State where pineapples are grown is Hawaii. Therefore, deriving 96% to 97 % of the cattle dietary burden for endosulfan from pineapple processed residue is unreasonable.

GLN 860.1500 Crop Field Trials

EPA Comments: Additional residue data are required for:
Barley hay; Oat forage and hay; Rye forage; Wheat forage, hay, and aspirated grain fractions; Rape forage; Sugarcane; Pea (dried) seed

ETF Response: Rape forage - ETF members requested use-deletion in 1999 for the rapeseed crop (including canola); Peas (dried/seed crop only) – the FIFRA 6(f)(l) use deletion was published in 62 FR 6776-6777, dated 2/13/97 and 63 FR 13246-13248, dated 3/18/98; Sugarcane – ETF does not support the US tolerance for this crop.

EPA Comments: Additional residue data also requested for turnip root.

ETF Response: With this response, the Task Force is making a new request to the Agency for translation of carrot and potato residue data to support the turnip root. The existing acceptable residue studies for carrot and potato roots showed residue levels to be < 0.05 ppm (lower than the existing tolerances of 0.2N). We will propose similar tolerance for the turnip root based on these root crop data. The justification for our request is as follows:

> The treatment rate for turnip is 1x0.75 lb. ai/acre with a 21 day PHI while that of potato is 6x1-lb. ai/acre with a 1 day PHI and carrot is 1x1lb ai/acre with a 7 day PHI. With the lower use rate (significantly in the case of potatoes) and the significantly longer PHI for turnips, translation of the data and establishment of a new turnip root tolerance based on the carrot and potato data is justified (0.2 ppm or lower). In addition, all of the turnips growing regions are represented by the carrot and potato residue trials.

EPA Comments: Possible residue data for cotton gin-byproducts from cotton treated with endosulfan before bolls opened might be required.

ETF Response: Recent field trial data exist for cotton gin-byproducts from cotton treated with endosulfan after bolls open. These studies (MRID Nos.: 44854101 and 44854102) had been reviewed and found acceptable to support a new tolerance of 28 ppm for the combined residues of endosulfan. The approval statements by the reviewer are as follow (DP Barcode No.: D258716, memo by Sherrie Mason dated December 10, 1999):

> The Agency stated that "*no cotton gin-byproducts data reflecting treatments made to cotton plants until bolls open have been submitted; however, because residues are expected to be lower from this use pattern, RRB2 will not require additional cotton gin byproducts data for reregistration. The registrant must submit a Section F proposing a tolerance for cotton gin byproducts. RRB2 recommend a tolerance of 28 ppm…"*

EPA Comments: In the Agency HED Chapter memo (by John S. Punzi dated 1/18/2000), it was stated that "the required limited field rotational crop study conducted on representative crops for the root and tuber vegetables, leafy vegetables, and small grains was recently submitted and will be reviewed"

ETF Response: With this response, we are requesting that the Agency review the study and inform us the review results as soon as possible. It should be noted that the protocol used for the study was pre-approved by the Agency and the field rotational crop study was conducted for sugar beets and wheat.

EPA Comments: "Confirmatory tobacco residue data" are required.

ETF Response: As stated by the Agency, such confirmatory data is a new requirement for use of pesticidal chemicals on tobacco. Based on our preliminary review, some tobacco residue data conducted with endosulfan are available within the Task Force companies and a few appeared to have been on file at the Agency. ETF needs clarification regarding this issue, and which data are still being required.

EPA Comments: Agency statements and the last paragraph on page 68 (Memo by S. Devitos dated 2/17/00), DP Barcode D250471) appears to contain errors. The beginning statement for that paragraph reads as *"endosulfan is presently not registered to members of the Endosulfan Task Force for use on mustard seed, raspberries, sugarcane, and watercress. IF registrants other than members of…"*

ETF Response: We believe there is an entry error for the "watercress". Instead, the crop referred to appear to be for "rapeseed", basing on the statements that follow which refers to 'canola oil '. More importantly, as noted in the Task Force letters

submitted in July to November of 1999, the Task Force is supporting the existing tolerances for raspberries (0.1 ppm) and mustard seeds (0.2N), although these crops are currently not listed on the main product labels. We are not aware of any additional residue data requirement for keeping these existing tolerances. Also, there exist interests through IR-4 involvement to establish a caneberries subgroup tolerance of 0.1 ppm (raspberry and blackberry, IR-4 data)
For sugarcane, the Task Force is not supporting the US tolerance for sugarcane, as noted in the top section above.

GLN 860.1520 Processed Food/Feed

EPA Comments: Acceptable Processing Studies for: apple juice and wet pomace (6x); pineapple peel (7x), bran (41x), pulp and juice; cottonseed meal, oil, and hulls; grape juice and raisins; plums and prunes; potato flakes, chips, and wet peel; and tomato puree and paste (1.2x).

ETF Response: Endosulfan Task Force would agree that acceptable processing studies exist for these matrices.

Status for A Submitted Study

The Task Force wishes to bring to the Agency attention the status of one submitted residue chemistry study (MRID No.: 44762901). The study is titled as "Magnitude of Endosulfan Residues in or on Wheat Grain and Processed Commodities Resulting from Two applications of Phaser® Insecticide in an Exaggerated Rate, USA, 1998", by S. Scott Brady, Residue Chemistry Department, AgrEvo/Aventis CropScience USA. February 1999 (Aventis Record No.: C000915). We submitted the study in early 1999 and based on our record, the report had been reviewed and found acceptable by HED pending the submission of the required storage stability data (memo by Stephen DeVito dated 5/27/99; DP Barcode No D253976). However and for reasons unclear to us, the Agency made no mention of this study in the Agency references or of its contents in the HED Chapters.

V. TASK FORCE RESPONSE TO THE DIETARY EXPOSURE CHAPTER

ENDOSULFAN TASK FORCE RESPONSE TO HED's RISK ASSESSMENT FOR THE ENDOSULFAN REREGISTRATION ELIGIBILITY DECISION DOCUMENT, DATED FEBRUARY 2, 2000

DIETARY EXPOSURE ANALYSIS CHAPTER

RE: Endosulfan: HED Risk Assessment for the Endosulfan RED Document (DP Barcode: D250471; Memo by Stephen C. DeVito, Ph.D., dated February 17, 2000) - Exposure Assessment,Section 4.3 "Risks from Dietary (Food and Drinking Water Sources) Exposure to Endosulfan", and

Anticipated Residues, Acute and Chronic Exposure Analysis for Endosulfan (DP Barcode: D260589; Memo by Sherrie L. Mason, dated November 10,1999)

Endosulfan Task Force Comments:

The Endosulfan Task Force (ETF) would first like to commend the Agency for performing a refined Tier-3 risk assessment for endosulfan. This risk assessment incorporates the latest policy and thinking on risk assessment inputs, processes and methods such as: Decompositing of monitoring data for single serving residue distributions, the assignment of values for non-detected/non-quantified residues in human health risk assessment, the latest "level of blending" Standard Operating Procedure, etc. The many registered commodities and wide array of available data for endosulfan makes this a complex task. The resulting EPA risk assessment gives an acceptable chronic and acute dietary risk picture for all currently registered endosulfan agricultural uses. The ETF feels confident that these acceptable dietary exposure levels can be even further refined by incorporation of the few error corrections and comments listed below. The screening level drinking water assessment done by the Agency also shows no concern for drinking water based on the registered uses. However the ETF would like to point out some errors in the modeling estimates that would result in even less concern when the Drinking Water Levels of Comparison (DWLOCs) are compared to Drinking Water Estimated Concentrations (DWECs). Also we would like to re-emphasize that available endosulfan water monitoring data for surface and ground water referenced in EPA's section on water monitoring (HED chapter, Section 4.3.b.2, p.35) show that the DWECs are several magnitudes higher than any detections of Endosulfan, which occurred, in a small percentage of the vast amount of analyzed samples. HED stated in comparing the results of model estimates with the available monitoring data that " *The monitoring data indicate however, that EFED's simulation models tend to overestimate actual concentrations of Endosulfan residues in surface and groundwater"* (HED chapter, p.35). The modeled estimates thus evidently overestimate any potential endosulfan water residues in surface and groundwater, and therefore lead to even less concern for drinking water exposure and its risk.

Specific Errors or Comments:

1. **Food Consumption Database**: EPA has used the DEEM™ program and the 1989-92 CSFII consumption database to estimate dietary exposures to endosulfan.

ETF comments: The 1994-96 CSFII consumption database is now available for use in the DEEM™ program. This database would be more reflective of the latest eating habits of the US consumers. Additionally, the follow up efforts on outliers and errors in the CSFII database has tended to be more rigorous in recent years and should lead to more reliable estimates of exposure for the populations.

2. **FQPA safety factor of 3 xs:** the default FQPA safety factor was retained at 3x for those subpopulations comprised of infants, children, and females of childbearing age.

ETF comments: The ETF believes and has provided appropriate comments within ETF's Toxicology Chapter Response that a threefold FQPA safety factor should not be retained based on the Agency's evaluation*: " based on the results of animal studies conducted under OPPTS guidelines there is no evidence of increased sensitivity or susceptibility of the fetus, infants or children to the toxicity of Endosulfan "*(HED chapter, p.3).

3. **Processing Factors**: EPA used default processing factors available in DEEM™.

ETF Comments: The ETF member companies have submitted many processing studies to EPA for the various endosulfan commodities during the Endosulfan Reregistration Process. These studies have been reviewed and accepted by EPA. The factors and data generated by these processing studies should be incorporated in the endosulfan risk assessments. These include the new processing studies for grapes, potatoes, tomatoes, and wheat plus the existing studies on file at the Agency for apples/pome fruits and other stone fruits. References to most of these data were cited in the current HED Residue Chapter dated February 2, 2000. The wheat processing data was not mentioned, but our records show that it had been reviewed by HED in July 1999 (memo by Steve DeVito, DP Barcode D253976).

4. **Decompositing of PDP Monitoring Data**: The Agency used the most recent methodology for dietary risk assessments.

ETF comments: We commend the Agency for applying this recently developed method to the risk assessment. However, it is not clear from the draft chapters which method EPA used for decompositing. Recently three methods were discussed at the March 1, 2000 SAP "Comparison of Allender, RDFgen and MaxLIP Decomposition Procedures." It was clear at this SAP that the different methods can affect the outcome of the distribution and possibly the risk assessment and also that EPA does not at this time endorse one method over the others. Thus a reference to which decompositing method that EPA had incorporated would be helpful.

5. **Endosulfan Crops Included in EPA Assessment:** The Agency's assessment used crops/commodities in excess of what the ETF is presently supporting.

   ETF comments: EPA included several crops in their risk assessment, which the ETF does not support and which have been deleted from the current ETF labels. Therefore these crops should not be included in the RED risk assessments. These deleted crops are (FR Notice Vol.62, p.5398-5399, February 5,1997): alfalfa (grown for forage), artichokes, field corn, peas (dried/seed crop only), safflower, sugarbeets, sunflower, and watercress. Alfalfa was included as a component of the ruminant dietary burden calculations and thus this calculation is incorrect.

6. **Calculation of Drinking Water Estimated Concentration Values**: The EPA calculated the peak and chronic surface water EEC value as 12 ug/L and 2ug/L, respectively.

   ETF Comments: The ETF does not agree with these calculated surface water numbers for use in endosulfan drinking water assessment. EPA calculations had not incorporated the 300 foot buffer zone, which is required by the ETF end-use product labels. As such, EPA's DWEC calculations result in a more conservative overestimation than is anticipated under actual uses. The ETF has recently addressed this issue in its submissions (MRID No: 44953105 and a comment document submitted in January, 2000 in response to EFED memo by D. Young dated 10/29/99). these documents the impact of the 300 foot buffer zone was considered and resulted in estimates for the surface water EECs of 0.89 μg/L (peak EEC for total endosulfan residues (α, β and sulfate) and 0.05 μg/L (chronic EEC for total residues) respectively. It should also be noted that these calculated EEC's were almost identical to the values found in the NLM's HSDB for various parts of the USA and Canada. For example the peak concentration observed was 0.9 μg/L. Although the Agency DWECs do not exceed the calculated DWLOCs, it is still important for the record that the Agency should use DWEC values for endosulfan drinking water exposure that account for the 300 foot buffer included in the ETF labels.

VI. TASK FORCE RESPONSE TO THE OCCUPATIONAL EXPOSURE ASSESSMENT CHAPTER

ENDOSULFAN TASK FORCE RESPONSE TO HED's RISK ASSESSMENT FOR THE ENDOSULFAN REREGISTRATION ELIGIBILITY DECISION DOCUMENT, DATED FEBRUARY 2, 2000

OCCUPATIONAL EXPOSURE ASSESSMENT CHAPTER

RE: Endosulfan: HED Risk Assessment for the Endosulfan RED Document (DP Barcode: D250471; Memo by Stephen C. DeVito, Ph.D., dated February 17, 2000) - Exposure Assessment, Section 4.4a –Exposure and Risks from Occupational Use of Endosulfan; and

"Occupational and Residential Exposure Assessment and Recommendation for the Reregistration Eligibility Decision Document for Endosulfan: (DP Barcode: D253711; memo by Renee Sandvig and Jack Arthur, dated February 2, 2000)

The Endosulfan Task Force (ETF), comprised of Aventis CropScience, FMC, and Makteshim Agan North America, has evaluated the occupational exposure and risk assessment prepared by the Agency on February 2, 2000.[1] In this response the ETF is addressing only those issues related to the formulated end-use products, use sites, used rates, and application methods, that are being supported by the ETF. The use sites supported by the ETF include agricultural crops, commercially grown outdoor trees, and shrubs, as well as commercially grown greenhouse tomatoes. The methods of application that are presently supported by the ETF include groundboom application, aerial application, chemigation and air blast application. The ETF is in support of the emulsifiable concentrate (EC) liquid formulation and the wettable powder (WP) formulation packaged with and without water-soluble bags. Issues relating to other sites, application methods, and formulations such as residential uses, hand applications, and dust formulations or the smoke canister formulation are beyond the scope of the ETF's response.

1. Duration of Exposure

The occupational exposure assessment erroneously defines the duration of intermediate-term and long-term exposure. The document defines intermediate-term exposure as 8 to 30 days and long-term exposure as 31 days to a year.

These duration definitions are inconsistent with the terminology defined by the Hazard Identification Assessment Review Committee (HIARC) and the duration definitions used in the HIARC review of endosulfan.[2] Intermediate-term exposure has been defined by HIARC as 7

[1] Occupational and Residential Exposure Assessment and Recommendations for the Reregistration Eligibility Decision Document for Endosulfan. Memorandum from Renee Sandvig to Steve DeVito. 2 February 2000.
[2] ENDOSULFAN-Report of the Hazard Identification Assessment Review Committee. Memorandum from David Liem and Jess Rowland to Steve DeVito. 7 October 1998.

days to several months and long-term exposure has been defined as several months to lifetime. This inconsistency should be addressed in corrections to the occupational assessment chapter.

The use patterns of endosulfan do not produce long-term occupational exposure and the Agency's assessment correctly does not calculate any long-term occupational exposure. Table 2 of the occupational assessment document should delete the columns pertaining to long-term dermal and inhalation exposure assessment, as these assessments are not relevant to the endosulfan exposure assessment.

Comments concerning the used toxicological endpoints of concern for Endosulfan (NOAELdermal = 3 mg/kg/day), as well as the FQPA safety factor (3 x) will be addressed separately in the ETF's response to HED's Toxicology Chapter.
The comments in this response will mainly address the exposure part of the assessment.

2. PHED Exposure Estimates

Reference 7 of the Agency occupational exposure risk assessment cites the May 1997 version of the PHED surrogate exposure guide used by the Agency in lieu of actual PHED product relevant subsets. A more recent August 1998 version of the surrogate guide exists and should have been used. Because the differences between the two versions are minimal and did not affect the endosulfan evaluation, the more recent version may well have been used. The citation should be updated if applicable.

All labels supported by the ETF are consistent with the Worker Protection Standard requirements for personal protective clothing (PPE). The PPE requirements for EC-formulations include coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves, and the use of chemical-resistant headgear during overhead spraying and chemical-resistant apron when cleaning, mixing and loading. The PHED estimates of unit exposure for the PPE scenarios reflect the use of the protective gloves and the double layer of clothing. However, the PPE scenario unit exposure estimates for air blast applications and flagging do not reflect the requirement for the use of chemical-resistant headgear during these overhead applications. An exposure mitigation factor should be applied to the head and neck exposure component of the air blast applicator and flagger dermal exposure estimates to account for the exposure reduction obtained by the label required protective headgear.

The ETF realises that the PHED surrogate exposure guide does not propose an exposure mitigation value for headgear as it does for double-layers of clothing, protective gloves, or respiratory protection. The ETF is unaware of the reason for this omission. Based on a 50% reduction in dermal exposure to the head and neck by the use of the protective headgear, the total dermal exposure to an air blast applicator using open-cab equipment is reduced from 0.22 mg/lb a.i. to 0.12 mg/lb a.i. Likewise, the flagger dermal exposure is reduced from 0.01 mg/lb a.i. to 0.007 mg/lb a.i. to reflect the 50% reduction in head/neck exposure afforded by the required headgear protective equipment. The ETF requests that the Agency either incorporates the exposure reduction afforded by the required headgear or provides a clear rationale of policy as why such headgear protection is not incorporated into the exposure assessment.

3. Airblast Applicator Exposure PHED Anomaly

The Agency has estimated the exposure to an applicator in an enclosed cab during airblast application by using the PHED surrogate guide estimate of 0.019 mg/lb a.i. for the single layer of clothing and protective glove scenario, but increasing the hand exposure estimate of 0.0129 mg/lb a.i. with protective gloves, 10-fold to estimate the exposure without gloves. This extrapolation is necessary because PHED does not contain any exposure data for airblast applicators in enclosed cabs in which protective gloves are not worn. The no-glove scenario is necessary because an applicator using engineering controls such as an enclosed cab is not required to use protective gloves.

Because of the absence of no glove hand data, the Agency back-calculated from the gloved hand exposure of 0.0129 mg/lb a.i. to no-glove hand exposure by using the 90% glove protection default. This increased the hand exposure to 0.129 mg/lb a.i. and the total dermal exposure to 0.14 mg/lb a.i. Despite the significant decrease in total dermal exposure that is produced by the use of enclosed cabs, the engineering control estimate is almost the same as the open cab airblast exposure estimate of 0.22 mg/lb a.i.

The error in the back-calculation results from the use of the 90% protection default that is appropriate in scenarios where no engineering controls exist to a scenario involving engineering controls. Because the enclosed cab is so efficient in reducing dermal exposure (0.197 mg/lb a.i. to 0.00418 mg/lb a.i. or 98% for the head and 0.0421 mg/lb a.i. to 0.00186 mg/lb a.i. or 96% for the torso and limbs) the addition of protective gloves in an enclosed cab will not reduce the unprotected hand exposure an additional 90%. The total deposition of dermal exposure outside the clothing to the arms, legs, and torso of an airblast applicator was 1.86 mg/lb a.i. in an open cab and 0.045 mg/lb a.i. in an enclosed cab. The enclosed cab reduced dermal deposition 98%. Therefore a comparison of open cab to enclosed cab deposition indicates a 95% to 98% reduction in exposure and an additional 90% reduction in hand exposure from gloves is unlikely.

The 90% default for hand exposure reduction by protective gloves of the applicators is not realistic. This can be ascertained by comparing the hand dermal exposure estimates for groundboom applicators. The hand exposure to open-cab groundboom applicators was 0.0065 mg/lb a.i. without gloves and 0.00629 mg/lb a.i. with gloves. There is essentially no difference, and hand exposure without gloves was not 10-fold higher than with gloves for the applicator. Similarly, hand exposure for groundboom applicators in enclosed cabs are nearly identical with gloves at 0.0009 mg/lb a.i. and 0.000836 mg/lb a.i. without gloves. The exception to this rule involves open cab airblast applicators where the protective gloves were efficient in reducing the heavy mist deposition. Unprotected hand exposure was 0.123 mg/lb a.i. compared to 0.00243 mg/lb a.i. when gloves were a barrier to the deposition of the airblast mist. Such deposition does not occur in the enclosed cab.

Because the use of the 90% default back-calculation is inappropriate for a combined enclosed-cab and protective glove scenario, the ETF proposes that the PHED data be used to select a more appropriate default for the enclosed cab airblast applicator hand exposure. Based on the 95% to 98% reduction in dermal exposure to the head and torso/limbs a 95% reduction in the bare hand open-cab dermal exposure estimate of 0.123 mg/lb a.i. is an appropriate default to estimate bare hand exposure for applicators in an enclosed airblast sprayer. The estimated hand exposure is

0.0062 mg/lb a.i. and the total dermal exposure to an airblast applicator in an enclosed cab is 0.012 mg/lb a.i. The HED occupational exposure assessment should correct these errors in their assessment for hand exposure.

4. Mixer/Loader and Applicator MOE Calculations

The Agency estimated the MOEs for mixer/loaders and applicators based on the type of mixing/loading operation and the application equipment used along with the standard HED default acreage and several application rates (worst case, not always represented by the ETF labels) within each exposure scenario. The ETF knows that this is the standard approach employed by HED for operator exposure and risk assessment. However, this approach is incorrect and inconsistent with the requirements of FIFRA that require a risk/benefit based regulatory decision-making process. As the risks and benefits of endosulfan vary for each individual crop and application scenario, the Agency's approach to estimating occupational exposure and risk must also be crop-specific, in accordance with the current ETF end-use product labels. The exposure scenario approach as used by HED in the occupational risk assessment is only useful as a screening approach for identifying potential risks based on extremely conservative default assumptions. Therefore the ETF considers the assessment as incorrect. The key crop specific information, necessary to conduct an accurate, specific exposure assessment was submitted by ETF to the Agency on 28 September 1999. This document appears to have been evaluated by HED based on comments in the third bullet of the "Data Quality and Confidence in Assessment" section (page 50 of the occupational risk assessment). But it appears that this information, based on actual use data, was not utilised by the Agency. It seems that HED did not understand how the ETF estimates were arrived at and that HED believes that the magnitude of the differences were not sufficient to significantly impact the assessment.

The ETF would like to provide HED with any assistance to ensure that the most appropriate data set is used. ETF would like to discuss with HED the submitted exposure estimates in more detail. The sources of information used by the ETF are all readily available to the Agency for confirmation. These sources were the U.S. Census Bureau of Agriculture, the Agency's own Quantitative Use Assessment, the 1996 Doane Marketing Survey, and the Pesticide Handlers Exposure Database surrogate guidance document estimates of exposure. The daily exposure algorithm was essentially the same one used by EPA to estimate exposure and the equations are provided in the ETF submission. Therefore we are concerned to see why the Agency has problems to understand how the submitted estimates were arrived at. Because the ETF submission remains germane to the endosulfan occupational risk assessment, a detailed review with specific, rather than broad stroke comments are necessary.

The second comment by the Agency that the magnitude of the difference between the ETF estimates and the Agency estimates is incorrect for certain crops. One would expect, and one finds, minimal differences when the average acreage for a specific crop is similar to the Agency acreage default value. However, for crops such as apples, watermelons, tomatoes, and tobacco there is a significant difference between the groundboom and airblast default acreage and the average acreage for these crops as reported in the Census of Agriculture, as well as the actual application rates. It is important to address the exposure and risk on a crop basis because different risk mitigation options become more obvious than using the Agency exposure scenarios. For example, a PPE MOE of 80 at a 3.0 lb a.i./A application may broadly indicate

that engineering controls are required using the current Agency exposure scenario set-up. However on a crop specific basis this same estimate of 80 may permit the determination that reducing the maximum application rate for that crop to 2.25 lb a.i./A would still maintain efficacy and permit continued use of the label-required PPE. The risk-benefits analysis required by FIFRA may indicate that endosulfan use on this crop has high benefits and that the MOE of 80 is acceptable based on high benefits.

A correct assessment of occupational exposure requires a crop-specific based assessment to permit the FIFRA mandated risk/benefits analysis.

5. Postapplication Exposure

The ETF submitted endosulfan-specific dislodgeable foliar residue (DFR) studies to the Agency (MRID# 44403102) for use in the calculation of restricted entry intervals (REIs). The studies were conducted in three representative crop groupings, melons for low crops, peaches for tree crops, and grapes for high trellised crops in accordance with Guideline 875.2000 guidance. In addition, the ETF also quantified the DFRs within each crop grouping for the emulsifiable concentrate (EC) and wettable powder (WP) formulations. The guidance document provides discussion that different formulations may produce different DFR dissipation profiles for similar uses on the same crops. Indeed, the endosulfan studies demonstrated that the dissipation curves for the liquid and wettable powder formulations were different. The HED occupational exposure assessment acknowledges the difference in the DFR values between the EC- and WP-formulations. The Agency erred in selecting only the WP DFR data to calculate the REIs for endosulfan because it represents the worst-case. Because the two formulations have different dissipation curves the formulation-specific dissipation curves must be used to set the formulation-specific REIs. Therefore, the WP DFR data are appropriate for WP- labels only and the EC DFR data are to be used to set REIs specific for EC- labels as is consistent with the intent of the 875.2000 guidelines.

The transfer coefficients (TCs) used by the Agency in the endosulfan postapplication exposure assessment are default values consistent with Policy Memo Number 3.[3] As stated in the background of the memo, the default values are a reference when no agricultural postapplication exposure data are available. The Endosulfan ETF members are also members of the Agricultural Reentry Task Force(ARTF) and as such may cite and utilise data submitted to the Agency by the ARTF. The ETF is therefore emphasising to the Agency that data submitted by ARTF must be used and that the Policy 3 default values are to be used only in the absence of data.

The ETF is concerned about an internal and deliberative HED memorandum of 25 February 1999 from Jack Arthur.[4] That memorandum appears to imply that if data from one study are substantially different from the default TCs, the data from the study should not be used as a surrogate in lieu of the default TC. Specific to the citrus situation addressed by the memorandum, the memorandum concluded that *it would not be appropriate to use the results from the one study resulting in a TC of 2000, for all other pesticide/citrus harvesting scenarios -- that is what our default values were specifically designed to do.*

[3] U.S. EPA. Policy Memo #003 from Science Advisory Council for Exposure. Agricultural Default Transfer Coefficients. 7 May 1998.
[4] U.S. EPA. Citrus TC's and Study Data Transferability. 25 Februay 1999.

The ETF understands the Agency’s concern that the results from any study may differ from either their default TC or the results of other studies (either completed or planned). The Agency's collective experience understands that the TC value for any given crop/activity will be variable when comparing the results of individual studies. Ideally the TC will be obtained from the results of several similar studies, which will supersede the results of one individual study. However, the results of one or more studies are to be used in place of a default coefficient, even if the result does not agree with the predetermined default. The following table contains a tabulation of worker reentry studies submitted by ARTF to the Agency. The data from these studies are to be used in lieu of the default TCs as is consistent with Policy

Agricultural Reentry Task Force

Revised December 14, 2001

Study No.	Study Title	EPA Submission Date	EPA MRID Number
ARTF Study reports that have been submitted to EPA:			
---	Agricultural Worker Crop Contact from Reentry Activities Performed in the USA and Canada: Grower Results	01/20/99	44802601
ARF003	Validation of Methods for the Analysis of Worker Exposure and Reentry Matrices for Diazinon and Malathion	11/12/99	44972204
ARF006	Determination of the Field Recovery and Stability of Diazinon and Malathion for Use in ARTF Reentry Exposure Studies	11/12/99	44972205
ARF007	Determination of the Freezer Storage Stability of Diazinon and Malathion on Matrices Used in Field Exposure Studies	11/12/99	44983501
ARF004	Validation of Method for the Analysis of Worker Exposure and Reentry Matrices for Chlorothalonil	12/23/99	45005901
ARF005	Determination of the Field Recovery and Stability of Chlorothalonil for Use in ARTF Generic Transfer Coefficient Studies	12/23/99	45005902
ARF019	Determination of the Field Recovery and Stability of Carbaryl for Use in ARTF Generic Transfer Coefficient Studies	12/23/99	45005903
ARF009	Determination of Dermal and Inhalation Exposure to Reentry Workers During Scouting in Sweet Corn	12/23/99	45005904
ARF010	Determination of Dermal and Inhalation Exposure to Reentry Workers During Harvesting in Sweet Corn	12/23/99	45005905
ARF011	Determination of Dermal and Inhalation Exposure to Reentry Workers	12/23/99	45005906

Study No.	Study Title	EPA Submission Date	EPA MRID Number
	During Scouting in Cauliflower		
ARF012	Determination of Dermal and Inhalation Exposure to Reentry Workers During Harvesting in Cauliflower	12/23/99	45005907
ARF021	Determination of Dermal and Inhalation Exposure to Reentry Workers During Scouting in Dry Peas	12/23/99	45005908
ARF022	Determination of Dermal and Inhalation Exposure to Reentry Workers During Scouting in Sunflowers	12/23/99	45005909
ARF023	Determination of Dermal and Inhalation Exposure to Reentry Workers During Scouting in Grapes	12/23/99	45005910
ARF024	Determination of Dermal and Inhalation Exposure to Reentry Workers During Harvesting in Tobacco	12/23/99	45005911
Purchased study reports that have been submitted to EPA:			
BASF	Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Strawberry		430130-04
BASF	Worker Reentry Exposure While Harvesting Strawberries Treated with Ronilan DF Fungicide in California		430130-03
BASF	Dissipation of Dislodgeable Foliar Residues of Vinclozolin (Ronilan DF Fungicide) Applied to Orchards – California and Georgia Sites		428300-01
BASF	Worker Reentry Exposure While Harvesting Stone Fruit Treated with Ronilan DF Fungicide in California		428300-02
Bayer	Evaluation of Reentry Exposure Following Application of BAYLETON® Fungicide to an Apple Orchard		424281-01
Bayer	Evaluation of Worker Exposure to Tribufos During harvesting of Cotton Treated with DEF6		427016-01
Novartis	Worker Reentry Exposure to Profenofos in Cotton Treated with Curacron		428513-02

Study No.	Study Title	EPA Submission Date	EPA MRID Number
	8E		
Dow Agro	Worker Reentry Exposure to Chlorpyrifos in Citrus Treated with Lorsban 4E Insecticide		430627-01
Dow Agro	Lorsban 4E and 50W Insecticides: Assessment of Chlorpyrifos Exposure to Applicators, Mixer/Loaders, and Reentry Personnel During and Following Application to Low Crops		429745-01
Dow Agro	Lorsban 4E and 50W Insecticides: Assessment of Chlorpyrifos Exposure to Applicators, Mixer/Loaders, and Reentry Personnel During and Following Application to Low Crops		429745-01
Uniroyal	Propargite Dislodgeable and Total Residues on Peach and Nectarine Foliage		409753-07
Uniroyal	Omite 30W on Peaches – Worker Reentry		409753-08
Uniroyal	Omite 30W Dislodgeable and Total Residues on Grape Foliage		409753-02
Uniroyal	Omite 30W Worker Reentry Study on California Grapes		409753-04
Uniroyal	Omite 6E on Almonds – Foliar Dislodgeable		418486-03
Uniroyal	Omite 6E on Almond – Worker Reentry Study		418486-04
Uniroyal	Method Validation and Determination of Freezer Storage Stability of Propargite Residues in Worker Exposure Study Samples		418486-09
Uniroyal	Omite 30W on Peaches: Propper Reentry Study		432976-02
Uniroyal	COMITE® on Cotton: Weeder Reentry Study		426891-03
Uniroyal	COMITE® on Beans: Weeder Reentry Study		426891-04
Valent	Dissipation of Dislodgeable Foliar Residues of Dibrom 8 Emulsive Applied to Grapes		432239-04
Valent	Worker Reentry Exposure While Harvesting Grapes Treated with Dibrom 8 Emulsive		432239-07
Captan TF	Worker Exposure to Residues of Captan 50-WP During Peach Harvest in		409665-01

Study No.	Study Title	EPA Submission Date	EPA MRID Number
	California		
Captan TF	Captan 50-WP Dislodgeable Residue Study on California Peaches		409886-04
Captan TF	Worker Exposure to Residues of Captan 50WP During Grape Harvest in California		409856-01
Captan TF	Captan 50WP Dislodgeable Residue Study on California Grapes		409886-03
Captan TF	Worker Exposure to Residues of Captan 50WP During Tomato Harvest in California		409665-03
Captan TF	Captan 50WP Dislodgeable Residue Study on California Tomatoes		409886-02
Captan TF	Worker Exposure to Residues of Captan 50WP During Strawberry Harvest in California		409665-02
Captan TF	Captan 50WP Dislodgeable Residue Study on California Strawberries		409886-01

The submitted ARTF studies listed above that contain DFR and worker reentry exposure data that permit the calculation of transfer coefficients can be broadly classified into the following categories:

- Scouting and Weeding
- Low crop harvesting
- Medium crop harvesting
- High crop harvesting
- Grapes harvesting/turning
- Tree harvesting

There are nine studies that looked at reentry exposure during weeding and scouting in sweet corn, cauliflower, dry peas, sunflowers, grapes, cotton, and beans. The ARTF estimated TCs ranged from 36 cm^2/hr to 1,180 cm^2/hr. The geometric mean TC is 153 cm^2/hr, which reflects the preponderance of TCs at the lower end of the range.

Two strawberry harvesting studies and a tomato harvesting study had TCs of 874 cm^2/hr and 1,266 cm^2/hr, and 611 cm^2/hr, respectively. The geometric mean of 878 cm^2/hr should be used in place of the low potential hand harvest default of 2,500 cm^2/hr. Likewise, the medium height harvesting TCs from two studies (4,290 for cauliflower and 725 for tobacco) 1,764 cm^2/hr should be used in place of the medium potential hand harvesting TC of 4,000 cm^2/hr.

ARTF has submitted three studies in which TCs are available for grape harvesting and other high contact grape activities. The TCs were 3,927 cm^2/hr, 6,840 cm^2/hr, and 2,928 cm^2/hr with a geometric mean TC of 4,284 cm^2/hr. This databased TC should replace the default 15,000 cm^2/hr used in the absence of data. The geometric TC for harvesting tree crops was 2,011 cm^2/hr obtained from four studies and should replace the default TC of 10,000 cm^2/hr.

The ETF understands that additional DFR and TC data will be submitted by the ARTF, however the magnitude of refinement in the TCs will be limited compared to the significant refinement obtained in going from the default values to the data derived TCs calculated by ARTF. Therefore, any reticence on the part of HED to use submitted reentry data are outweighed by the regulatory obligation to utilise all submitted data that meet guideline requirements.

The impact of using the ARTF based TCs in lieu of the default TCs and using the endosulfan EC- DFR data rather than the WP- formulation data, which are appropriate only for the wettable powder formulation, is significant on the estimation of the correct REIs.

An example of the impact is illustrated with harvesting tomatoes. Table 14 of the HED assessment for occupational exposure estimated a 32-day REI for tomatoes based on a 3 lb a.i./A application rate, a wettable powder based DFR of 0.024 $\mu g/cm^2$, and a TC of 10,000 cm^2/hr based on tomatoes being considered a high potential exposure crop. In reality, the ARTF scoping effort would place tomatoes in the low crop cluster with a harvesting TC of 878 cm^2/hr. The ARTF tomato harvesting study submitted to the Agency had a TC of 611 cm^2/hr. The label maximum application rate for tomatoes is 1.0 lb a.i./A and not the generic 3.0 lb a.i./A used by HED. Therefore the 3-fold increase in the melon DFR values to adjust from the study application rate of 1.0 lb a.i./A to the generic 3.0 lb a.i./A rate is inappropriate. This further

illustrates why the endosulfan REIs must be calculated on a crop specific basis and not on crude clusters that do not account for the different application rates.

Using the ARTF data derived TC of 878 cm^2/hr, an 8-hour workday, 70-kg bodyweight, and the dermal NOEL of 3 mg/kg/day (EPA's used endpoint), the DFR value that provides a 100 fold MOE is 0.3 $\mu g/cm^2$.[5] Based on the endosulfan DFR data, dislodgeable residues of 0.3 $\mu g/cm^2$ or less are reached on Day 2 for the EC and Day 5 for the WP. Therefore the Agency should propose REIs of 48 hours for the EC and 5 days for the WP on tomatoes, rather than the 32 days calculated in the occupational assessment. Based on the NOEL of 9 mg/kg/d the calculated REI would be less than 24 hours for the EC and less than 48 hours for the WP.

The ETF concludes that the correct estimation of the REIs in the HED risk assessment must account for the different dissipation curves of the two distinguished formulations as provided by the submitted DFR data. It must also account for the crop-specific application rates, the appropriate toxicological endpoint, and must utilise the TC values from studies submitted by the ARTF rather than default values intended for use in the absence of data. The ETF is planning to submit a refined assessment for occupational postapplication exposure, using the available use data (similar to the one submitted with the mixer/loader/applicator assessment), resulting in crop- and activity-specific REI calculations.

The ETF considers HED's occupational risk assessments as very preliminary, extremely conservative and not reflective of reality. The safety of the use of Endosulfan has been proven over the last four decades since it has been in the market. The ETF is not aware of any incidents or worker illnesses when the product has been used according to the existing labelling. This safety record is also being evidenced by information available from the Incident Data System (memo J.Blondell, EPA January 18, 2000).

[5] 3,000 $\mu g/kg/day$ x 70 kg ÷ 8 hr/day ÷ 878 cm^2/hr = 30 $\mu g/cm^2$
30 $\mu g/cm^2$ ÷ 100 fold uncertainty factor = 0.30 $\mu g/cm^2$

VIII. TASK FORCE SUBMITTED STUDIES NOT YET INCLUDED/REVIEWED IN THE CURRENT HED CHAPTERS DATED FEBRUARY 2, 2000.

We have noted that the current HED Chapters for endosulfan have not included the contents or Agency reviews for several keys reports submitted by the Task Force during October to November, 1999. We request that the Agency will review these relevant studies as soon as possible so that the information can be incorporated into the next revised HED Chapters for public comments. The studies include the following:

1. Toxicology (MRID No. 44939102) - Submitted on October 4, 1999, tilted as "Endosulfan – Evaluation of Possible Endocrine Effects in Mammalian Species", by J. N. Bremmer and K.-H. Leist, Hoechst Schering AgrEvo GmbH, Frankfurt, Germany, December 18, 1999 (AgrEvo/Aventis Record No.: C001570)

2. Application Worker Exposure (MRID No.: 44939101) – Submitted on October 4, 1999, titled as "Assessment of Human Exposure from the Application of Endosulfan", by Kelly White. Jellinek, Schwartz & Connolly Inc. September 28, 1999 (AgrEvo/Aventis Record No.: C002873)

3. Dietary (Water) Exposure (MRID No.: 44953105) – Submitted on October 15, 1999, titled as "Endosulfan: Calculation of Dietary Exposure via Drinking Water and Comparison to Drinking Water Level of Concern" by Richard Allen. AgrEvo/Aventis CropScience USA. October 8, 1999 (AgrEvo/Aventis Record No.: B002594)

4. Residue Chemistry (MRID No.: 44972301) – Submitted on November 15, 1999, tilted as "Magnitude of Endosulfan Residues in or on Rotational Crops Resulting from Two applications of Phaser® Insecticide, USA, 1998", by S. Scott Brady, Residue Chemistry Department, AgrEvo/Aventis CropScience USA. November 5, 1999 (AgrEvo/Aventis Record No.: B002616)

5. Residue Chemistry (MRID No.: 44762901) – Submitted in November 1998, titled as "Magnitude of Endosulfan Residues in or on Wheat Grain and Processed Commodities Resulting from Two applications of Phaser® Insecticide in an Exaggerated Rate, USA, 1998", by S. Scott Brady, Residue Chemistry Department, AgrEvo/Aventis CropScience USA. February 1999 (Aventis Record No.: C000915). The studied had been reviewed and found acceptable by HED pending the submission of the required storage stability data (memo by Stephen DeVito dated 5/27/99; DP Barcode No D253976). However, for reasons unclear to us, the Agency made no mention of this study in the Agency references or of its contents in the HED Chapters